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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/810,768	03/26/2004	William F. Niland	HQS-107US	9079
23122	7590	07/11/2007	EXAMINER	
RATNERPRESTIA			MITCHELL, TEENA KAY	
P O BOX 980			ART UNIT	PAPER NUMBER
VALLEY FORGE, PA 19482-0980			3771	
			MAIL DATE	DELIVERY MODE
			07/11/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

ED

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/810,768	NILAND ET.AL.	
	Examiner	Art Unit	
	Teena Mitchell	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 13 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 16-18, 20-39 and 42-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16-18, 20-39, 42-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

  
TEENA MITCHELL  
PRIMARY EXAMINER

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Arguments***

Applicant's arguments with respect to claims 16-18, 20-39, 42-45 has been considered but is moot in view of the new ground(s) of rejection.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 16, 21-27, 32, 34-38, and 42-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson (3,912,795) in view of Ko ('527)

Jackson in a humidification system discloses a supply unit (Fig. 1) configured to deliver humidified gas; a delivery tube assembly (at 10) having a delivery tube (Fig. 1) with a proximal end and a distal end, said delivery tube assembly also having a fitting positioned at said proximate end (at 12) of said delivery tube and releasably coupled to said supply unit (Fig. 1), said delivery tube assembly being configured to transfer heat to the humidified gas received from said supply unit (Fig. 1). The difference between Jackson and claim 16 is a nasal cannula releasably coupled to the distal end of the delivery tube to receive humidified gas from the delivery tube of the delivery tube

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assembly. Ko. (Col. 10, lines 29-31) teaches a releasable nasal cannula (148) or an endotracheal tube to a connector member (146) of a gas delivery tube providing a means for releasably connecting a plurality of different patient interfaces to a gas delivery conduit. It would have been obvious to substitute the respiratory device of Jackson with a nasal cannula because it would have provided a means for releasably connecting a plurality of different patient interfaces to a gas delivery device as taught by Ko, therefore the substitution of a nasal cannula for the respiratory delivery device of Jackson would have been obvious to one of ordinary skill in the art one respiratory delivery device for another.

Regarding claim 20, Ko teaches a releasable coupling (146).

Regarding claim 21, Ko teaches an adaptor (144).

Regarding claim 22, Jackson discloses wherein said fitting of said delivery tube assembly being configured for releasable connection to said supply unit (Figs. 1, 5, 6).

Regarding claim 23, Jackson discloses wherein said gas supply unit having a gas inlet (Fig. 1 below).

Regarding claim 24, Jackson discloses means for receiving gas from a source of gas and for delivering the gas to said gas inlet of said supply unit (Fig. 1).

Regarding claim 25, Jackson discloses a gas receiving means comprising a tube (Fig. 1).

Regarding claim 26, Jackson discloses said gas receiving means further comprising a fitting configured for connection to the source of gas (Fig. 1).

Regarding claim 27, Jackson discloses said supply unit having a liquid inlet configured to receive supplemental liquid (Fig. 1).

Regarding claims 32, 39, 42-45, note rejections of claims 16-18, 20-27 above. The claimed method steps would have been obvious because they would have resulted from the use of the device of Jackson/Ko.

Regarding claim 34, Jackson discloses the claimed invention note rejections of claim 16 above, Jackson also discloses wherein the breathing gas is humidified by fluid that has flowed through and reverses direction in the delivery tube (Fig. 1).

Regarding claim 35, note rejection of claim 16 above.

Regarding claim 36, Jackson discloses wherein the fluid flow through the system is configured such that the fluid heats the breathing gas prior to humidifying the breathing gas (Fig. 1).

Regarding claims 37 and 38, note rejection of claim 16 above and the teaching by Ko of a nasal cannula.

Regarding claims 42-45, the claimed method steps would have been obvious because they would have resulted from the use of the device of Jackson/Ko rejected above.

**Claims 28-31, 33, 17, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson ('795) in view of Ko ('527) as applied to claims 16-18, 20-27 above, and further in view of McComb ('946) and Koch (6,367,472).**

Regarding claim 28, Jackson does not disclose a source of supplemental liquid coupled to said liquid inlet. Koch in a humidification device teaches a water fed via a

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line based upon static pressure providing a means to ensure the fibers are surrounded by water on the outside (Col. 4, lines 58-62). It would have been obvious to one of ordinary skill in the art to provide a supplemental liquid coupled to the liquid inlet because it would have provided a means to ensure the fibers are surrounded by water on the outside as taught by Koch.

Regarding claim 29, Koch teaches a water supply bag (9, Col. 4, lines 58-62).

Regarding claim 30, Jackson/Ko discloses the claimed invention except for the supply unit being configured to delivery to deliver humidified gas at a flow rate of about 1 liter per minute to about 8 liters per minute.

McComb, in a system for delivering humidified gas to a patient, teaches a supply unit being configured to deliver humidified gas at flow rates between 3 to 150 liters/minute which includes a flow rate of about 1 liter per minute to about 8 liters per minute for the purpose of accommodating a patient's differing respiratory capacities and for accommodating a ventilator alone or a ventilator in combination with an anesthesia circuit (Col. 5, lines 48-61). It would have been obvious to modify the device of Jackson to provide a wide range of flow rates including 1-6 liters per minute because it would have provided a means for accommodating patient's having differing respiratory capacities and for accommodating a ventilator alone or a ventilator in combination with an anesthesia circuit as taught by McComb. Jackson also does not disclose the limitation of the relative humidity in a range of about 95% to about 100%. Koch in a humidifier device teaches relative humidity established a nearly constant humidification of the air fed in the range of 90% to 100% providing flow of gas, which is always

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humidified uniformly in continuous operation and in intermittent operation (Col. 2, lines 21-33). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the flow rate at a relative humidity of 90% to 100% (which falls within the claimed parameters) because it would provide a flow of gas which is always humidified uniformly in continuous operation and in intermittent operation as taught by Koch.

Regarding claims 31 and 33 note rejection of claim 30 above.

Regarding claims 17 and 18, note rejection of claim 30 above.

### ***Conclusion***


The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The balance of art is cited to show humidification devices: 6,976,489 and 6,474,628.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teena Mitchell whose telephone number is (571) 272-4798. The examiner can normally be reached on Monday-Friday however on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Teena Mitchell  
Primary Examiner  
Art Unit 3771  
July 5, 2007

TKM  
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